



Patent  
Case No.: 58281US004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: NOELLE, RANDOLPH J.

Application No.: 10/748010 Group Art Unit: 1653

Filed: December 30, 2003 Examiner: Unknown

Title: IMMUNOSTIMULATORY COMBINATIONS

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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31 Aug. 2004  
Date

Laci Burhop  
Signed by: Laci Burhop

Dear Sir:

Pursuant to 37 CFR §§ 1.56, 1.97, and 1.98, enclosed is a completed Form PTO-1449, citing references submitted for consideration by the Examiner. Copies of any cited foreign patents, non-patent literature, and unpublished US application documents are enclosed. Pursuant to the waiver in the Pre-OG Notice, dated July 11, 2003, copies of US patents and published US patent applications are no longer required and are not enclosed. It is respectfully requested that the Examiner initial and return the enclosed Form PTO-1449 to indicate that each reference has been considered.

If a first Office Action on the merits has been mailed prior to the mailing date of this document, please charge the fee for consideration of an Information Disclosure Statement set forth in 37 CFR § 1.17(p), and if necessary, please charge any additional fees, or credit any overpayment to Deposit Account No. 13-3723.

Respectfully submitted,

Date

31 August 2004

By:

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Application Number

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Randolph J. Noelle

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U.S. Patent Documents					
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		Doc. Number-(Kind Code if Known)			
	A1	US- 4,689,338	08-25-1987	Gerster	
	A2	US- 4,698,348	10-06-1987	Gerster	
	A3	US- 4,929,624	05-29-1990	Gerster et al.	
	A4	US- 4,988,815	01-29-1991	Andre et al.	
	A5	US- 5,037,986	08-06-1991	Gerster	
	A6	US- 5,175,296	12-29-1992	Gerster	
	A7	US- 5,238,944	08-24-1993	Wick et al.	
	A8	US- 5,266,575	11-30-1993	Gerster et al.	
	A9	US- 5,268,376	12-07-1993	Gerster	
	A10	US- 5,346,905	09-13-1994	Gerster	
	A11	US- 5,352,784	10-04-1994	Nikolaides et al.	
	A12	US- 5,367,076	11-22-1994	Gerster	
	A13	US- 5,376,501	12-27-1994	Mariën et al.	
	A14	US- 5,389,640	02-14-1995	Gerster et al.	
	A15	US- 5,395,937	03-07-1995	Nikolaides et al.	
	A16	US- 5,446,153	08-29-1995	Lindstrom et al.	
	A17	US- 5,482,936	01-09-1996	Lindstrom	
	A18	US- 5,494,916	02-27-1996	Lindstrom et al.	
	A19	US- 5,525,612	06-11-1996	Gerster	
	A20	US- 5,605,899	02-25-1997	Gerster et al.	
	A21	US- 5,693,811	12-02-1997	Lindstrom	
	A22	US- 5,741,908	04-21-1998	Gerster et al.	
	A23	US- 5,756,747	05-26-1998	Gerster	
	A24	US- 5,939,090	08-17-1999	Beaurline et al.	
	A25	US- 6,028,076	02-22-2000	Hirota et al.	
	A26	US- 6,039,969	03-21-2000	Tomai et al.	
	A27	US- 6,069,149	05-30-2000	Nanba et al.	
	A28	US- 6,083,505	07-04-2000	Miller et al.	

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## U.S. Patent Documents

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		Doc. Number-(Kind Code if Known)			
	A29	US- 6,110,929	08-29-2000	Gerster et al.	
	A30	US- 6,113,918	09-05-2000	Johnson et al.	
	A31	US- 6,194,388 B1	02-27-2001	Krieg et al.	
	A32	US- 6,194,425 B1	02-27-2001	Gerster et al.	
	A33	US- 6,200,592 B1	03-13-2001	Tomai et al.	
	A34	US- 6,207,646 B1	03-27-2001	Krieg et al.	
	A35	US- 6,239,116 B1	05-29-2001	Krieg et al.	
	A36	US- 6,245,776 B1	06-12-2001	Skwierczynski et al.	
	A37	US- 6,303,347 B1	10-16-2001	Johnson et al.	
	A38	US- 6,323,200 B1	11-27-2001	Gerster et al.	
	A39	US- 6,329,381 B1	12-11-2001	Kurimoto et al.	
	A40	US- 6,331,539 B1	12-18-2001	Crooks et al.	
	A41	US- 6,339,068 B1	01-15-2002	Krieg et al.	
	A42	US- 6,376,501 B1	04-23-2002	Isobe et al.	
	A43	US- 6,376,669 B1	04-23-2002	Rice et al.	
	A44	US- 6,387,938 B1	05-14-2002	Mizuguchi et al.	
	A45	US- 6,406,705 B1	06-18-2002	Davis et al.	
	A46	US- 6,426,334 B1	07-30-2002	Agrawal et al.	
	A47	US- 6,440,992 B1	08-27-2002	Gerster et al.	
	A48	US- 6,476,000 B1	11-05-2002	Agrawal	
	A49	US- 6,451,810 B1	09-17-2002	Coleman et al.	
	A50	US- 6,514,985 B1	02-04-2003	Gerster et al.	
	A51	US- 6,518,265 B1	02-11-2003	Kato et al.	
	A52	US- 6,518,280 B2	02-11-2003	Gerster et al.	
	A53	US- 6,525,028 B1	02-25-2003	Johnson et al.	
	A54	US- 6,525,064 B1	02-25-2003	Dellaria et al.	
	A55	US- 6,541,485 B1	04-01-2003	Crooks et al.	
	A56	US- 6,545,016 B1	04-08-2003	Dellaria et al.	

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<b>Examiner Name</b>	Unknown
<b>Attorney Case Number</b>	58281US004

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	A57	US- 6,545,017 B1	04-08-2003	Dellaria et al.	
	A58	US- 6,558,951 B1	05-06-2003	Tomai et al.	
	A59	US- 6,573,273 B1	06-03-2003	Crooks et al.	
	A60	US- 6,649,172 B2	11-18-2003	Johnson	
	A61	US- 6,656,938 B2	12-02-2003	Crooks et al.	
	A62	US- 6,660,735 B2	12-09-2003	Crooks et al.	
	A63	US- 6,660,747 B2	12-09-2003	Crooks et al.	
	A64	US- 6,664,260 B2	12-16-2003	Charles et al.	
	A65	US- 6,664,264 B2	12-16-2003	Dellaria et al.	
	A66	US- 6,664,265 B2	12-16-2003	Crooks et al.	
	A67	US- 6,667,312 B2	12-23-2003	Bonk et al.	
	A68	US- 6,670,372 B2	12-30-2003	Charles et al.	
	A69	US- 6,677,347 B2	01-13-2004	Crooks et al.	
	A70	US- 6,677,348 B2	01-13-2004	Heppner et al.	
	A71	US- 6,677,349 B1	01-13-2004	Griesgraber	
	A72	US- 6,683,088 B2	01-27-2004	Crooks et al.	
	A73	US- 2002/0016332 A1	02-07-2002	Slade	
	A74	US- 2002/0055517 A1	05-09-2002	Smith	
	A75	US- 2002/0058674 A1	05-16-2002	Hedenstrom et al.	
	A76	US- 2002/0110840 A1	08-15-2002	Tomai et al.	
	A77	US- 2003/0133913 A1	07-17-2003	Tomai et al.	
	A78	US- 2003/0139364 A1	07-24-2003	Krieg et al.	
	A79	US- 2003/0144283 A1	07-31-2003	Coleman et al.	
	A80	US- 2003/0199461 A1	10-23-2003	Averett et al.	
	A81	US- 2004/0010007 A1	01-15-2004	Dellaria et al.	
	A82	US- 2004/0014779 A1	01-22-04	Gorden et al.	

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## Foreign Patent Documents

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		Ctry. Code	Number-KindCode (If known)				
	B1	EP	0 394 026	10-24-1990			X
	B2	EP	1 104 764 A1	06-06-2001			X
	B3	JP	9-208584	08-12-1997			
	B4	JP	11-80156	03-26-1999	(translation only)		X
	B5	JP	11-222432	08-17-1999			X
	B6	JP	2000-247884 (abstract only)	09-12-2000			X
	B7	WO	00/47719 A2	08-17-2000			X
	B8	WO	00/75304 A1	12-14-2000			X
	B9	WO	00/76505 A1	12-21-2000			X
	B10	WO	00/76518A1	12-21-2000			X
	B11	WO	01/74343 A2	10-11-2001			X
	B12	WO	02/072032	09-19-2002			
	B13	WO	02/36592 A1	05-10-2002			X
	B14	WO	02/46188 A2	06-13-2002			X
	B15	WO	02/46189 A2	06-13-2002			X
	B16	WO	02/46190 A2	06-13-2002			X
	B17	WO	02/46191 A2	06-13-2002			X
	B18	WO	02/46192 A2	06-13-2002			X
	B19	WO	02/46193 A2	06-13-2002			X
	B20	WO	02/46194 A2	06-13-2002			X
	B21	WO	02/46749 A2	06-13-2002			X
	B22	WO	02/085905 A1	10-31-2002			
	B23	WO	02/102377 A1	12-27-2002			X
	B24	WO	03/020889 A2	03-13-2003			X
	B25	WO	03/043572 A2	05-30-2003			X
	B26	WO	03/045391 A1	06-05-2003			X
	B27	WO	03/103584 A2	12-18-2003			X

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OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)			
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	C1	Testerman, et al., "Cytokine Induction by the Immunomodulators Imiquimod and S-27609", <u>Journal of Leukocyte Biology</u> , Volume 58, pp. 365-372, September 1995.	
	C2	Chollet, et al, "Development of a Topically Active Imiquimod Formulation", <u>Pharmaceutical Development and Technology</u> , 4(1), pp 35-43 (1999)	
	C3	Brassard et al.; "Interferon- $\alpha$ as an immunotherapeutic protein"; <u>Journal of Leukocyte Biology</u> ; Vol. 71; April 2002; pgs. 565-581	
	C4	Izumi et al.; "1H-imidazo[4,5-c]quinoline Derivatives as Novel Potent TNF- $\alpha$ Suppressors: Synthesis and Structure-Activity Relationship of 1-, 2-and 4-Substituted 1H-imidazo[4,5-c]quinolines or 1H-imidazo[4,5-c]pyridines"; <u>Bioorganic and Medicinal Chemistry</u> , Vol. 11, pp. 2541-2550 (2003).	
	C5	Hornung et al., "Quantitative Expression of Toll-Like Receptor 1-10 mRNA in Cellular Subsets of Human Peripheral Blood Mononuclear Cells and Sensitivity to CpG Oligodeoxynucleotides <sup>1</sup> ", <u>The Journal of Immunology</u> , 2002, 168; pgs. 4531-4537.	
	C6	Hemmi et al., "Small anti-viral compounds activate immune cells via the TLR7 MyD88-dependent Signaling pathway", <u>Nature Immunology</u> , vol. 3, no. 2; February 2002; pgs. 196-200.	
	C7	Medzhitov, "Toll-Like Receptors and Innate Immunity", <u>Nature Reviews Immunology</u> , Vol. 1; November 2001, pgs. 135-145.	
	C8	Jurk et al. "Human TLR7 and TLR8 independently confer responsiveness to the antiviral compound R-848", <u>Nature Immunology</u> , June 2002, vol. 3, no. 6; pg. 1.	
	C9	Akira et al., "Toll-like receptors: critical proteins linking innate and acquired immunity", <u>Nature Immunology</u> , August 2001, vol. 2, no. 8; pgs. 675-680	
	C10	Heil et al.; "Synthetic immunostimulatory compounds activate immune cells via TLR7 and TLR8"; 33th Annual Meeting of the Deutsche Gesellschaft für Immunologie, Marburg 2002 - Abstract C.6	
	C11	Takeuchi et al.; "Discrimination of bacterial lipoproteins by Toll-like receptor 6", <u>International Immunology</u> , March, 2001, Vol. 13, No. 7, pp. 933-940.	
	C12	Maxwell et al.; "Contrasting the Roles of Costimulation and the Natural Adjuvant Lipopolysaccharide During the Induction of T Cell Immunity", <u>J. Immunol.</u> , May 2002; Vol. 168, pp. 4372-4381.	
	C13	Maxwell et al, Danger and OX40 Receptor Signaling Synergize to Enhance Memory T Cell Survival by Inhibiting Peripheral Deletion, <u>J. Immunol.</u> , Jan. 2000; Vol. 164, pp. 107-112.	
	C14	Lamprecht et al.; "Heterogeneity of CD4+ and CD8+ Memory T Cells in Localized and Generalized Wegener's Granulomatosis", <u>Arthritis Res. and Ther.</u> , 2003; Vol. 5, pp. R25-R31.	
	C15	Mackay,; "Dual Personality of Memory T cells", <u>Nature</u> , 1999; Vol. 401, pp. 659-660.	
	C16	Weninger et al.; Migratory Properties of Naïve, Effector, and Memory CD8+ T Cell, <u>J. Exp. Med.</u> , Oct. 2001; Vol. 194, No. 7, pp. 953-966.	
	C17	Faint et al.; "Memory T Cells Constitute a Subset of the Human CD8+CD45RA+ Pool with Distinct Phenotypic and Migratory Characteristics", <u>J. Immunol.</u> , 2001, Vol. 167, pp. 212-220.	
	C18	Kedl et al.; "CD40 Stimulation Accelerates Deletion of Tumor-Specific CD8+ T Cells in the Absence of Tumor-Antigen Vaccination", <u>Proc. Nat. Acad. Sci.</u> , Sept. 2001; Vol. 98, No. 19, pp. 10811-10816.	
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	C19	Kedl et al, "T Cells Compete for Access to Antigen-Bearing Antigen-Presenting Cells", <u>J. Exp. Med.</u> , Vol. 192, No. 8, pp. 1105-1113.

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